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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,851	08/29/2003	Richard G. Cartledge	28099-0005	8124

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HOGAN & HARTSON LLP  
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WASHINGTON, DC 20004

EXAMINER
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SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/651,851

Applicant(s)

CARTLEDGE ET AL.

Examiner

Thomas J. Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 23-39 is/are pending in the application.
- 4a) Of the above claim(s) 35-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 23-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments, see page 6, filed 1/11/2007, with respect to traversal of the restriction have been fully considered and are persuasive. The election is treated as an election with traverse, but no arguments were submitted traversing the restriction, so the restriction is not traversed.

Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection.

### ***Election/Restrictions***

Newly submitted claims 35-39 are directed to an invention that is independent or distinct from the prior elected species of figs 4-5 and 9 for the following reasons: figs 4-5 require element 135 an adjustment tool as disclosed. The newly submitted claims 35-39 utilize a micromotor rather than the adjustment tool. These species are directed to related methods for controlling the internal circumference of an anatomic orifice or lumen. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the

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inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant has received an action on the merits for the elected invention. Accordingly, claims 35-39 are withdrawn from consideration as being directed to a non-elected invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmadi et al in view of Forsell (US 6,067,991). Ahmadi et al discloses a method for controlling the internal circumference of an anatomic orifice or lumen, comprising the steps of:

stopping the flow of physiological fluids through an anatomic orifice or lumen (col 5, lines 15-16); introducing an adjustable implant device adjacent to said anatomic orifice or lumen (col 5, lines 20-34), said implant device substantially defining a plane (ring shaped);

securing the adjustable implant device to the tissue around adjacent said anatomic orifice or lumen (col 5, lines 27-29), wherein said adjustable implant device comprises a docking mechanism (52) configured to operably engage an adjustment tool (48) to adjust size or shape of said adjustable implant device;

resuming the flow of physiological fluids through said anatomic orifice or lumen (col 5, lines 47-49); and after said step of resuming the flow of physiological fluids, adjusting size or shape of

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said adjustable implant device using an adjustment tool operably engaged with said docking mechanism (col 5, lines 49-68), wherein said adjustment tool has a proximal portion (at 56) and a distal portion (at 49). However, Ahmadi et al does not disclose when operably engaged, at least the distal portion of said adjustment tool is disposed in a non-planar orientation with respect to said plane defined by said implant device. Forsell teaches another adjustment mechanism in the art of surgical devices wherein an adjustment tool (24) is disposed in a non-planar orientation with respect to said plane defined by said implant device (10) for the purpose of adjusting a ring device (26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the ring adjustment mechanism of Forsell (fig. 2) for the ring adjustment mechanism on the adjustable implant of Ahmadi et al in order to adjust a ring and such a modification amounts to mere substitution of one functionally equivalent ring adjustment mechanism for another in the art of surgical devices.

With regard to claim 4, wherein said step of manipulating said proximal portion of said adjustment tool gear comprises the a step of rotating said proximal portion of said adjustment tool gear from a location outside a said closed incision (see fig. 10).

With regard to claim 5, said step of gear manipulating said proximal portion of said adjustment tool from a location outside a said closed incision comprises a step of rotating said proximal portion of said adjustment tool while said distal portion of said adjustment tool is operably engaged with said docking mechanism effective to operate said adjustment mechanism effective to adjust a size or shape of said adjustable implant device (col 5-6, lines 47-23).

With regard to claim 23, said step of adjusting size or shape of the adjustable implant device is conducted under normal or near-normal physiologic conditions (col 5, lines 49-54).

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With regard to claim 24, further comprising a step of disengaging said adjustment tool from engagement with said docking mechanism without altering the adjusted size or shape of said adjustable implant device (inherent, the adjustment would not be useful unless maintained while removing the tool).

With regard to claims 25-28, further comprising a step of operably re-engaging said adjustment tool with said docking mechanism (col 6, lines 8-23).

With regard to claims 29 and 31, said step of adjusting size or shape of said adjustable implant device comprises reducing the size of said adjustable implant device (col 5, lines 57-59).

With regard to claims 30 and 23, said step of adjusting size or shape of said adjustable implant device comprises increasing the size of said adjustable implant device (col 5, lines 62-64).

With regard to claim 33, further comprising a step of adjusting size or shape of said adjustable implant device before said resuming step (inherently, there is a pre-adjustment prior to surgery in order to assemble the device).

With regard to claim 34, said further step of adjusting a size or a shape of said adjustable implant device before said closing step is performed. (col 5, lines 47-68)

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Several references are listed on the 892 form enclosed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tjs



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